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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,248	02/11/2002	Bernd Riedl	BAYER-15 P4	9631

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER

DESAI, RITA J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/071,248

Applicant(s)

RIEDL ET AL.

Examiner

RITA J. DESAI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 is/are allowed.
- 6) ☒ Claim(s) 17,18 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6. 6) ☐ Other: .

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 22-25, drawn to compounds , pharmaceutical composition and a method of treating using these compounds of formula Ia and Ib, classified in class 546 and 514 , subclass 290.298,300,303; 345,350,354,351.
- II. Claims 19-21, drawn to complex compositions, classified in class 514, 424 and various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as osteoporosis and the combination is for treating cancer. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Mr. Traverso on 12/6 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18, 22-25. Affirmation of this election must be made by applicant in replying to this Office action. Claim 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The abstract of the disclosure is objected to because it does not clearly disclose the invention related to the claims. A more accurate description of the claimed invention is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of enablement

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Claims 18 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the various cancers, does not reasonably provide enablement for the “prevention” of these diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specifications do not have any guidance as to the prevention of cancer.

In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

The specifications do not teach how to prevent cancer. In view of *the unpredictability* of diseases such as cancer it is unbelievable how one can prevent it without any guidance from the specification. It is hard enough just to treat cancer let alone “prevent” it.

Applicant is required to delete the term “preventing” from their claims.

#### Lack of Description

Claims 18 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no guidance in the specifications that would teach a person of skill in the art how the compounds prevent the various cancers since the treatment itself and let alone the prevention is a very unpredictable art.!

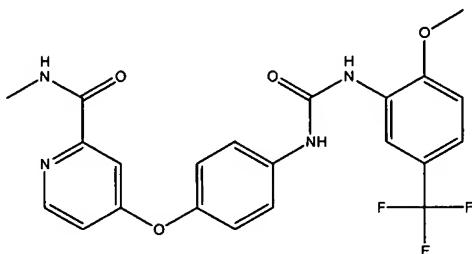
#### ***Double Patenting***

Claims 17, 18, 22-25 of this application conflict with claims 68-109 and 50-54 of Application No. 10/042203. 37 CFR 1.78(b) provides that when two or more applications filed

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by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim 74 of US 10042203 discloses the following compound.



N-(2-methoxy-5-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridyloxy)phenyl)urea

Claim 17, 18, 22-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 50-54, 68-109 of copending Application No. 10/042,203. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### Closest Prior Art:-

US 6143764 Kubo et al, teaches compounds which are useful in treating tumors but these compounds have a quinoline with methoxy substituents, instead of a pyridine which must have an amido group.

#### Conclusion

The compounds of claims 1-16 are found to be allowable over the prior art. If applicants overcome the other objections and rejections the claims may be allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "R.D. Desai", with a long horizontal line extending from the end of the signature.

R.D.

December 9, 2002